APPARATUS AND METHOD FOR VOLUME ADJUSTMENT OF INTRAGASTRIC BALLOONS

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention is directed to adjustment devices and methods that enable inflatable intragastric balloons used for the treatment of obesity to be filled, and in particular devices and methods that enable the intragastric balloon to be filled, adjusted or deflated from outside of the stomach through non-surgical means while the device itself is in the stomach.

2. DESCRIPTION OF THE RELATED ART

Intragastric balloons are well known in art as a means for treating obesity. One such inflatable intragastric balloon is described in U.S. Patent No. 5,084,061, and is commercially available as the BioEnterics Intragastric Balloon System (sold under the trademark BIB®). These devices are designed to provide therapy for moderately obese individuals who need to shed pounds in preparation for surgery, or as part of a dietary or behavioral modification program.

The BIB System, for example, consists of a silicone elastomer gastric balloon that is inserted into the stomach and filled with fluid. Commercially available gastric balloons are filled with saline solution or air. The gastric balloon functions by filling the stomach and enhancing appetite control. Placement of the gastric balloon is non-surgical, usually requiring no more than 20-30 minutes. The procedure is performed endoscopically in an outpatient setting, typically using local anesthesia and sedation. Placement is temporary, and gastric balloons are typically removed after six months.

Most gastric balloons utilized for this purpose are placed in the stomach in an empty or deflated state and thereafter filled (fully or partially) with a suitable fluid through a filler tube. The filler tube can be either removable or permanently attached to the balloon. The removable filler tube is typically attached prior to initial placement of the gastric balloon and then removed after inflation. The balloon occupies space in the stomach, thereby leaving less room available for food and creating a feeling of satiety for the obese person. Clinical results with these devices show that for many obese patients, the intragastric balloons significantly help to control appetite and accomplish weight loss.

Among the intragastric balloons described in the prior art, one type remains connected to a filler tube during the entire time period while the balloon is in the stomach. The balloon is introduced into the patient's stomach and a connected tube is extended through the nostril. Such an intragastric balloon is described, for example, in U.S. Patent No. 4,133,315.

Another type of intragastric balloon of the prior art is placed into the stomach with the assistance of an appropriate plastic tube and usually a stylette. The balloon is filled with saline, whereafter the tube and stylette are withdrawn from the stomach. An intragastric balloon of this second type is described, for example, in UK Patent Application GB 2 090 747.

Even for the balloons of the second type, it may become desirable, from time-to-time, to add more saline in order to further expand the balloon to optimize weight control. In addition, one means of removing the balloon is to deflate it by removing the saline from the balloon through a tube before the empty balloon is removed from the stomach.

To accomplish the foregoing, intragastric balloons of the second type are normally equipped with a self-sealing valve into which the filler tube and or stylette can be inserted. One difficulty frequently encountered in this type of intragastric balloon is finding the valve when the balloon is already in the stomach and the surgeon is attempting to reinsert the filler tube for the purpose of adding or removing fluid from the balloon. Those experienced in the art will readily appreciate that manipulating the balloon while *is situ* to visually locate the valve is rather difficult, and the process of searching for the valve undesirably prolongs the procedure. Moreover, even after the filler valve has been visually located, it is often still difficult or awkward for the surgeon to reinsert the tube into the filler valve. This is because the balloon is slippery and positionally unstable. In other words, the usually spherical (or substantially spherical) intragastric balloons readily rotate in the stomach, so that even a slight disturbance of the balloon may place the filler valve into virtually any possible position relative to the filler tube poised to engage it.

Another problem associated with the heretofore known methods and devices is that following placement of the gastric balloons, a patient may experience nausea form the interaction of the recently placed gastric balloon with the stomach. This

has been particularly noted when the gastric balloon is placed and filled to its capacity or substantially to its capacity in a single procedure.

Therefore, the present invention is directed at overcoming these problems associated with the prior art systems. These and other characteristics of the present invention will become apparent from the further disclosure to be made in the detailed description given below.

SUMMARY OF THE INVENTION

One aspect of the present invention is a gastric balloon including a shell, a receiver, and a retractable tubing housed in the receiver and extendable from the stomach of a patient to the mouth of the patient. The shell is inflated and deflated through the retractable tubing from outside the body of the patient.

Another aspect of the present invention is directed to a method of adding or removing fluid from an implanted gastric balloon by inserting a gastroscopic tool into the stomach of a patient and grasping an end of a retractable tubing housed in a receiver of the gastric balloon. Further steps of the method include withdrawing at least a portion of the retractable tubing from the stomach and out of the patient's mouth, and adding or removing fluid from the gastric balloon via the retractable tubing withdrawn from the patient.

Yet another aspect of the present invention is directed to a method of treating obesity. The method includes a step of implanting a gastric balloon including a shell, a receiver, and a retractable tubing housed in the receiver and extendable from the stomach of a patient to the mouth of the patient. The gastric balloon can be inflated and deflated through the retractable tubing from outside the body of the patient. A further step of the method entails inflating the gastric balloon to a first desired level to promote acclimatization of the gastric balloon in the stomach and to minimize nausea in the patient. Thereafter, the method entails a step of periodically increasing the inflation of the gastric balloon to subsequent desired levels known to minimize nausea and to achieve a continuous, regular, and safe rate of weight loss.

Further still, an aspect of the present invention is a method of implanting a gastric balloon including a step of providing a gastric balloon including a shell, a receiver, and a retractable tubing housed in the receiver and extendable from the stomach of a patient to the mouth of the patient. Further steps in the method include

removing the retractable tubing from the receiver to minimize the volume of the uninflated gastric balloon, and gastroscopically implanting the gastric balloon in the stomach of a patient while maintaining at least a portion of the retractable tubing outside the mouth of the patient. Thereafter the method includes inflating the gastric balloon to a desired level, and releasing the retractable tubing to promote retraction of the retractable tubing into the stomach of the patient with or without endoscopic assistance.

Further characteristics, features, and advantages of the present invention will be apparent upon consideration of the following detailed description of the invention taken in conjunction with the following drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a cross-sectional view of a retractable tube gastric balloon according to one embodiment of the present invention;

Fig. 2 is a cross-sectional view of a retractable tube gastric balloon according to a further embodiment of the present invention;

Fig. 3 is a cross-sectional view of a retractable tube gastric balloon according to another embodiment of the present invention;

Fig. 4 is a cross-sectional view of a retractable tube gastric balloon according to the present invention;

Fig. 5 is a cross-sectional view of a retractable tube gastric balloon according to yet another embodiment of the present invention; and

Fig. 6 is a cross-sectional view of a retractable tube gastric balloon according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed to a method and device for adjusting intragastric balloon volume *in vivo* or *in situ*, without removing the free-floating balloon from the stomach.

A gastric balloon 10 according to the present invention is shown in Figs. 1-6. The gastric balloon 10 includes a shell 12, a retractable tubing 16, and a receiver 14 for housing the retractable tubing 16. In one embodiment of the present invention, the retractable tubing 16 has a memory that returns it to the receiver 18 after being

withdrawn from the receiver 14 for adding or removing fluid from the gastric balloon 10.

During implantation, an uninflated balloon 10 may be placed in the stomach with the tubing extended through the esophagus in order to minimize the size of the mass passing down the esophagus. Following initial placement, a desired quantity of fluid may be added to the gastric balloon 10 via the retractable tubing 16, a portion of which extents from the gastric balloon 10 through the esophagus and out of the patient's mouth. In some instances, despite the retractable nature of the retractable tubing 16, gastroscopic instrument assistance may also be required to properly stow the retractable tubing 16 in the receiver 14. Such steps may be necessary both after initial inflation or subsequent use of the gastric balloon 10 and the retractable tubing 16.

A method of adding or removing fluid from the gastric balloon 10 according to the present invention requires that a gastric balloon according to the present invention, such as those shown in Figs. 1-6, be implanted in a patient. After implantation, inflating or deflating the gastric balloon 10 includes a step of accessing the retractable tubing 16 stowed on or in intragastric balloon 10. This accessing step is preferably performed gastroscopically. The retractable tubing 10, once accessed is grasped by a grasping tool (not shown), and a portion of the retractable tubing 10 is brought through the gastro-intestinal tract including the esophagus to the exterior of the patient via the mouth. Alternatively, the retractable tubing 10 could be brought through the nose of the patient without departing from the scope of the present invention. Next, using a syringe and needle or tubing with a shaped tip that is not injurious to the valve, fluid is added or removed through a self-sealing valve (not shown). The valve may be of a "Two Way Slit Valve" type described in commonly assigned international application number PCT US03/19414, the disclosure of which is incorporated herein by reference. Alternatively the valve could be a septum that is pierced by the needle or shaped tube tip, but resists flow of fluid out of the gastric balloon. The fluid enters the shell 12 of the gastric balloon 10 from the retractable tubing 16 through an interface 18. In some instances it may be desirable to include a valve at interface 18, or alternatively at both interface 18 and at an end of the retractable tubing 16 which is withdrawn from the patient to add or remove fluid.

Once a sufficient volume of liquid is added or removed from the gastric balloon, the retractable tubing 16 can be released. Upon release, the retractable tubing 16 will return to its stowed position inside or on the gastric balloon 10 in receiver 14, which remains in the stomach of the patient.

The housing and accessing of the retractable tubing 16 in or on the gastric balloon 10 has many advantages over the devices and methods of the prior art. Initially, this allows for much more careful regulation and oversight in addressing a plateau in weight loss during the course of the balloon's implantation. This is enabled by the ease with which fluid can be added or removed from the gastric band 10. Previously, the addition of fluid was a time-consuming and challenging process that tended to dissuade a medical professional and the patient from undertaking these procedures unless deemed absolutely necessary.

In that same vein, the retractable tubing 16 allows for much easier deflation and removal of the gastric balloon 10 at the end of its implantation period. Because of the difficulty in deflating prior art gastric balloons, other methods of removal of the gastric balloons were developed, including piercing the balloon to drain the fluid contained therein into the stomach before removal of the remains endoscopically. Naturally, such a method requires the insertion of a piercing or cutting instrument into the body. As with the insertion of an inflation tube with the prior art devices, the substantially round gastric balloons have a tendency to move, and can be difficult to grasp by the grasping and piercing tool. By eliminating the need for any such device from entering the body, the potential for injury from inadvertently piercing the stomach during the removal process is greatly reduced.

Further, it has been determined that the incidence of nausea caused by the implantation of a gastric balloon can be greatly reduced by allowing the stomach to initially acclimatize itself to the gastric balloon when it is filled to a low volume in the recommended range. This volume can then be increased in stages after the patient is acclimatized to the device. Typically, this can be done over a period of weeks until a desired volume is reached.

With this acclimatization period comes yet another benefit in that the fear of overly rapid weight loss can be substantially eliminated. This enables the medical professional to closely monitor weight loss rates and alter the volume of the gastric balloon accordingly, preventing both the plateaus discussed above, and rapid weight

loss which can have serious medical consequences. While some of the prior art devices could perform some of these similar functions, they could not be performed without substantial effort and time on the part of both the medical professional and the patient or serious inconvenience on the part of the patient.

In Fig. 1, the retractable tubing 16 is shown as a continuous coil. Various balloon shapes are required according to different tubing storage embodiments or receivers 14. Tubing stored in a coil requires a cylindrically shaped receiver 14 in the balloon surface as shown in Fig. 1. Tubing stored in a spiral, or stacks of spirals requires a shallower cylindrical recess or receiver 14 in the balloon 10 surface, as shown in Fig. 2. Another spiral configuration is that of a typical "yo-yo" toy, with the spiral beginning in a hemispherical groove receiver 14 and encircling the balloon multiple times and dividing the balloon into two hemispheres, as shown in Fig. 3. These combinations of retractable tubing 16 and receiver 14 are merely exemplary and other shapes and tubing arrangements are considered within the scope of the present invention.

The retractable tubing 16 may be soft and include a coil or radial spiral as a stiffener. Alternatively, semi-rigid tubing may be used that has been cured in a coil or spiral and has sufficient stiffness to return to this shape when released. In another embodiment, a superelastic shape memory alloy (SMA) may be used as a suitable coil spring to ensure that the retractable tubing 16 returns to the receiver 14 when not in use.

Another configuration includes a torsionally loaded axle 22 that self-retracts the retractable tubing 16, as shown in Figs. 5 and 6. The torsionally loaded axle 22 may be pre-grooved to assist in winding the retractable tubing 16 onto the axle 22 when released.

Also shown in Figs. 5 and 6 is a molded valve patch 24. In essence, the molded valve patch 24 is a receiver 14 formed separately from the shell 12. This molded valve patch 24 allows for separate construction and subsequent joining to the balloon shell 12. The molded valve patch 24 can have the retractable tubing 16 inserted and bonded to it prior to joining the shell 12. The shell 12 and the molded valve patch 24 may be joined together through a thermal or chemical bonding process. In some embodiments, this thermal or chemical bonding process may be performed in conjunction with an unvulcanized sheeting 26, as shown in Figs. 4-6.

A further embodiment of the present invention includes a receiver cover or hood 20 to reduce the possibility of the retractable tubing 16 becoming entangled with stomach contents or deposition of stomach contents on the retractable tubing 16 or inside of the molded valve patch 24. This cover or cap 20 may be attached to the tubing and may have a feature to make it easily accessed by standard gastroscopic instrumentation. The cap 20 may also contain a valve or septum as discussed above or alternatively could simply act as a plug for the retractable tubing 16.

Although the invention has been particularly shown and described with reference to certain preferred embodiments, it will be readily appreciated by those of ordinary skill in the art that various changes and modifications may be made therein without departing from the spirit and scope of the invention.